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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/913,516

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Katsumi Iga

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22428 7590 02/27/2007

FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

GEORGE, KONATA M

ART UNIT

PAPER NUMBER

1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	09/913,516	IGA ET AL.	
	Examiner	Art Unit	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8, 11-13, 15, 16, 18-34, 38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8, 11-13, 15, 16, 18-34, 38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 8, 11-13, 15, 16, 18-34, 38 and 39 are pending in this application.

Action Summary

1. The rejection of claim 34 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps is hereby withdrawn as applicant has amended the claim to overcome the rejection.
2. The rejection of claims 8, 11-13, 15, 16, 18-33, 38 and 39 under 35 U.S.C. 103(a) over SmithKline Beecham Co. in view of Sekine et al. and RxList Monographs is being maintained for the reasons stated in the previous office action.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 8, 11-13, 15, 16, 18-34, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over SmithKline Beecham Co. (WO 95/06410) in view of Sekine et al. (WO 97/28794 as translated by US 6,054,484) and RxList Monographs (1999).

SmithKline Beecham Co. ('410) discloses the use of angiotension II receptor antagonist as a medicament for the treatment of chronic inflammatory diseases, which can be formulated for transdermal delivery as a patch or membrane, and when formulating the composition topically the composition can contain non-toxic auxiliary substances such as emulsifying agent, polyols, etc. (page 28, lines 2-7 and page 29,

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lines 14-32). Claim 13, page 41, lines 29-33 of SmithKline Beecham Co. teach that the angiotension II receptor antagonist is 1-(cyclohexyloxycarbonyloxy) ethyl-2-ethoxy-1-[(2'-(1H-tetrazol-5-yl) biphenyl-4-yl) methyl]-benzimidazole-7-carboxylate or pharmaceutically acceptable salt. SmithKline Beecham Co. does not teach the preparation comprising a fatty acid ester or the angiotension II antagonistic activity.

Sekine et al. discloses in Table 14, a cataplasm (see col. 5, lines 25-31 for description) comprising a fatty acid ester (isopropyl myristate at a concentration of 1%), a polyol (propylene glycol at a concentration of 10%) and a nonionic surfactant (coconut fatty acid diethanolamide at a concentration of 2%) (col. 20, lines 1-22). Column 7, lines 13-18 of Sekine et al. describe a formulation of a self-adhesive cataplasm by adding a polymer (polybutene) and gelatin.

RxList Monograph discloses information about 1-(cyclohexyloxycarbonyloxy) ethyl-2-ethoxy-1-[(2'-(1H-tetrazol-5-yl) biphenyl-4-yl) methyl]-benzimidazole-7-carboxylate also known as Candesaratan cilexetil.

Sekine et al. teaches the preparations using diclofenac sodium as the active agent. Column 1, lines 53-60 of Sekine et al. teach that diclofenac sodium has 1.5% solubility in water. RxList Monographs teach that Candesaratan cilexetil is practically insoluble in water. Therefore, when formulating a compound that is poorly soluble in water such as Candesaratan cilexetil into a transdermal delivery system, one of ordinary skill in the art could look to Sekine et al. as a method of formulating a compound that has poor solubility in water into a transdermal delivery device with the addition of compounds that can aid in penetration i.e. polyols, surfactants and fatty acids.

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With respect to the angiotension II antagonistic activity, absent a clear showing of criticality, the determination of angiotension II antagonistic activity is within the skill of the ordinary worker as part of the process of normal optimization to achieve the desired results of the claimed composition.

Response to Arguments

4. Applicant's arguments filed November 7, 2006 have been fully considered but they are not persuasive.

Applicants argue that SmithKline Beecham Co. does not teach the permeability regulator comprising a fatty acid ester. Although it is not taught by the SmithKline Beecham reference to use a fatty acid ester in the device, it is known in the art that fatty acid esters are used as permeation enhancers as taught in column 6, lines 32-35 of Sekine et al. One of ordinary skill in the art would be motivated to add a permeation enhancer to a transdermal delivery device for the purposes of aiding in the deliver of large molecular weight compounds or compounds that would require additional help permeating through the skin.

Conclusion

5. Claims 8, 11-13, 15, 16, 18-34, 38 and 39 remain rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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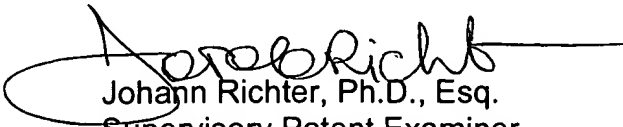
Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konata M. George
Patent Examiner
Technology Center 1600


Johann Richter, Ph.D., Esq.
Supervisory Patent Examiner
Technology Center 1600